

S/N 10/696,676



*IPW*

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Keith L. BLACK et al.

Examiner: Richard A. Schnizer

Serial No.: 10/696,676

Group Art Unit: 1635

Filed: October 29, 2003

Docket: 67789-503

Title: METHOD FOR USING POTASSIUM CHANNEL AGONISTS FOR  
DELIVERING A MEDICANT TO AN ABNORMAL BRAIN REGION AND/OR  
MALIGNANT TUMOR

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 et. seq., the referenced materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

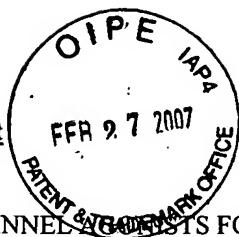
Also attached hereto are copies of Forms PTO-1449 listing references disclosed by Applicants in parent application No. 09/491,500, filed January 26, 2000 (now USP 7,018,979), of which the subject application is a continuation application. Examiner is requested to acknowledge that each of these references has been reviewed in connection with the present continuation application so that these references are printed on the cover page of any patent granted on the present application.

Supplemental Information Disclosure Statement

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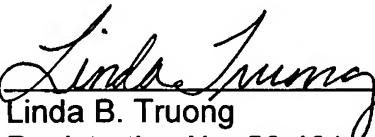
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Docket No. 67789-503

No fee is due pursuant to 37 C.F.R. §1.97(b)(4). If additional fees are believed necessary, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 04-0258.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

February 21, 2007

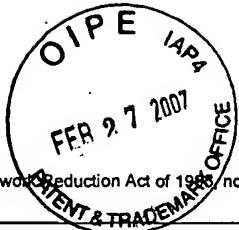
Respectfully submitted,  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <small>( Not for submission under 37 CFR 1.99)</small>	Application Number		10696676
	Filing Date		2003-10-29
	First Named Inventor		Keith L. Black
	Art Unit		1635
	Examiner Name		Richard A. SCHNIZER
	Attorney Docket Number		67789-503

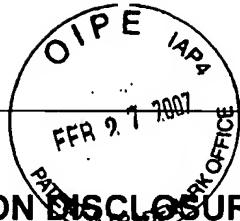
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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5011837		1991-04-30	Atwal et al.	
	2	5234922		1993-08-10	Welsh et al.	
	3	7018979		2006-03-28	Black et al.	
	4	6417207		2002-07-09	Garvey et al.	

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	1	20030072748		2003-04-17	Black et al.	
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#### FOREIGN PATENT DOCUMENTS



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	1	WO 01/54680			2001-02-07	Cedars-Sinai Medical Center		<input type="checkbox"/>
	2	WO 96/12030			1996-04-25	Rhone-Poulenc Rorer S.A.		<input type="checkbox"/>
	3	WO 01/54771			2001-08-02	Cedars-Sinai Medical Center		<input type="checkbox"/>

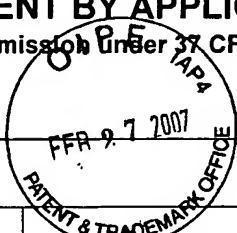
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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Black, Keith L. et al., Intracarotid infusion of RMP-7, a bradykinin analog, and transport of gallium-68 ethylenediamine tetraacetic acid into human gliomas, Journal of Neurosurgery, 86(4):603-609 (1997).	<input type="checkbox"/>
	2	Brayden, Joseph E., Functional roles of KATP channels in vascular smooth muscle, Clinical and Experimental Pharmacology and Physiology, 29(4):312-6 (2001).	<input type="checkbox"/>
	3	Brayden, J.E., Potassium channels in vascular smooth muscle, Clinical and Experimental Pharmacology and Physiology, 23(12): 1069-76 (December 1996). (ABSTRACT ONLY)	<input type="checkbox"/>
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6	Inamura, Takanori et al., Bradykinin selectively opens blood-tumor barrier in experimental brain tumors, <i>Journal of Cerebral Blood Flow Metabolism</i> , 14(5):862-870 (1994).	<input type="checkbox"/>
7	Janigro, Damir et al., ATP-sensitive K <sup>+</sup> channels in rat aorta and brain microvascular endothelial cells, <i>Department of Neurological Surgery, University of Washington</i> , C812-C821 (1993).	<input type="checkbox"/>
8	Joo, Ferenc et al., Regulation of the macromolecular transport in the brain microvessels: the role of cyclic GMP, <i>Brain Research</i> , 278:165-174 (1983).	<input type="checkbox"/>
9	Liebner, Stefan et al., Claudin-1 and claudin-5 expression and tight junction morphology are altered in blood vessels of human glioblastoma multiforme, <i>Acta Neuropathol</i> , 100:323-331 (2000).	<input type="checkbox"/>
10	Liu, Sju Ming et al., Nitric oxide and cGMP regulate endothelial permeability and F-actin distribution in hydrogen peroxide-treated endothelial cells, <i>Experimental Cell Research</i> , 235:238-244 (1997).	<input type="checkbox"/>
11	Shah, Shrenik P. et al., Drug delivery to the central nervous system: a review, <i>Journal of Pharmacy and Pharmaceutical Science</i> , 6(2):252-273 (2003).	<input type="checkbox"/>
12	Morimoto, Takashi et al., Increased levels of tissue endostatin in human malignant gliomas, <i>Clinical Cancer Research</i> , 8:2933-2938 (September 2002).	<input type="checkbox"/>
13	Nilaver, Gajanan et al., Delivery of herpesvirus and adenovirus to nude rat intracerebral tumors after osmotic blood-brain barrier disruption, <i>Proceedings of the National Academy of Science</i> , 92:9829-9833 (October 1995).	<input type="checkbox"/>
14	Ningaraj, Nagendra S. et al., Adenosine 5'-triphosphate-sensitive potassium channel-mediated blood-brain tumor barrier permeability increase in a rat brain tumor model, <i>Cancer Research</i> , 63:8899-8911 (December 15, 2003).	<input type="checkbox"/>
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16	Rothberg, Brad S. et al., Gating kinetics of single large-conductance Ca <sup>2+</sup> -activated K <sup>+</sup> channels in high Ca <sup>2+</sup> suggest a two-tiered allosteric gating mechanism, <i>Journal of General Physiology</i> , 114:93-124 (July 1999).	<input type="checkbox"/>

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17	Schoch, Heike J. et al., Hypoxia-induced vascular endothelial growth factor expression causes vascular leakage in the brain, <i>Brain</i> , 125:2549-2557 (2002). <input type="checkbox"/>
18	Stewart, Patricia A., Endothelial vesicles in the blood-brain barrier: are they related to permeability?, <i>Cellular and Molecular Neurobiology</i> , 20(2):149-163 (2002). <input type="checkbox"/>
19	Sugita, Masao et al., Cyclic GMP-specific phosphodiesterase inhibition and intracarotid bradykinin infusion enhances permeability into brain tumors, <i>Cancer Research</i> , 58(5):914-920 (1998). <input type="checkbox"/>
20	Tanaka, Yoshio et al., Molecular constituents of maxi K <sup>+</sup> channels in human coronary smooth muscle: predominant α + β subunit complexes, <i>Journal of Physiology</i> , 502(3):545-557 (1997). <input type="checkbox"/>
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22	Mackic, Jasmina B. et al., Cereport (RMP-7) increases the permeability of human brain microvascular endothelial cell monolayers, <i>Pharmaceutical Research</i> , 16(9):1360-1365 (1999). <input type="checkbox"/>
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25	Ransom, Christopher et al., BK channels in human glioma cells, <i>Journal of Neurophysiology</i> , 85:790-803 (2001). <input type="checkbox"/>
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	28	Abdul, M. et al., Activity of potassium channel-blockers in breast cancer, <i>Anticancer Research</i> , 23(4):3347-3351 (July-August 2003). (ABSTRACT ONLY)	<input type="checkbox"/>
	29	Baba, T. et al., Intracarotid infusion of leukotriene C4 selectively increases blood-brain barrier permeability after focal ischemia in rats, <i>Journal of Cerebral Blood Flow and Metabolism</i> , 11:638-643 (July 1991). (ABSTRACT ONLY)	<input type="checkbox"/>
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INFO SHEET	31	Black, Keith L., Imaging and drug delivery to tumor-infiltrated brain, <i>Clinical Neurosurgery</i> , Chapter 30: 563-572	<input type="checkbox"/>
INFO SHEET	32	Black, Keith L. et al., Increased opening of blood-tumor barrier by leukotriene C4 is dependent on size of molecules, <i>Neurological Research</i> , 14: 402-404, (1992).	<input type="checkbox"/>
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	37	Cloughesy, T.F. et al., Intra-arterial carboplatin chemotherapy for brain tumors: a dose escalation study based on cerebral blood flow, <i>Journal of Neuro-Oncology</i> , 35(2):121-131 (November 1997). (ABSTRACT ONLY)	<input type="checkbox"/>
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39	Elliot, P.J. et al., Unlocking the blood-brain barrier: a role for RMP-7 in brain tumor therapy, <i>Experimental Neurology</i> , 141(2):214-224 (October 1996). (ABSTRACT ONLY)	<input type="checkbox"/>
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41	King, Wesley A. et al., Intracarotid infusion of leukotriene C4 increases blood-tumor barrier permeability in experimental rat brain tumors, <i>Neurological Surgery Surgical Forum</i> , Volume XL:490-493 (1989).	<input type="checkbox"/>
42	Matsukado, K. et al., Steroids decrease uptake of carboplatin in rat gliomas - uptake improved by intracarotid infusion of bradykinin analog, RMP-7, <i>Acta Neurochirurgica Supplement</i> , 70:159-161 (1997). (ABSTRACT ONLY)	<input type="checkbox"/>
43	Matsukado, K. et al., Intracarotid low dose bradykinin infusion selectively increases tumor permeability through activation of bradykinin B2 receptors in malignant gliomas, <i>Brain Research</i> , 792(1):10-15 (May 4, 1998). (ABSTRACT ONLY)	<input type="checkbox"/>
44	Nakano, S. et al., Enhanced cytokines delivery and intercellular adhesion molecule 1 (ICAM-1) expression in glioma by intracarotid infusion of bradykinin analog, RMP-7, <i>Neurological Research</i> , 19(5):501-508 (October 1997). (ABSTRACT ONLY)	<input type="checkbox"/>
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47	Sugita, M. et al., Nitric oxide and cyclic GMP attenuate sensitivity of the blood-tumor barrier permeability to bradykinin, <i>Neurological Research</i> , 20(6):559-563 (September 1998). (ABSTRACT ONLY)	<input type="checkbox"/>
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	4A	Bang et al., Nitroglycerin-mediated vasorelaxation is modulated by endothelial calcium-activated potassium channels, <i>Cardiovascular Research</i> , 43(3):772-778 (August 15, 1999). (ABSTRACT ONLY)	<input type="checkbox"/>
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	51	Butt, E. et al., Inhibition of cyclic GMP-dependent protein kinase-mediated effects by (Rp)-8-bromo-PET-cyclic GMPS, <i>British Journal of Pharmacology</i> , 116(8): 3110-3116 (December 1995). (ABSTRACT ONLY)	<input type="checkbox"/>
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	54	Fullerton, D.A. et al., Effective control of pulmonary vascular resistance with inhaled nitric oxide after cardiac operation, <i>Journal of Thoracic Cardiovascular Surgery</i> , 111(4):753-762; discussion 762-763 (April 1996). (ABSTRACT ONLY)	<input type="checkbox"/>
	55	Gbadegesin, M. et al., Hypoxia modulated nitric oxide-induced regulation of NMDA receptor currents and neuronal cell death, <i>American Journal of Physiology</i> , 277(4 Pt 1):C673-683 (October 1999). (ABSTRACT ONLY)	<input type="checkbox"/>
	56	Goto, K. et al., Sympathetic control of arterial membrane potential by ATP-sensitive K(+)-channels, <i>Hypertension</i> , 35 (1 Pt 2):379-384 (January 2000) (ABSTRACT ONLY)	<input type="checkbox"/>
	57	Hardy, P. et al., A major role for prostacyclin in nitric oxide-induced ocular vasorelaxation in the piglet, <i>Circulation Research</i> , 83(7): 721-729 (October 5, 1998) (ABSTRACT ONLY)	<input type="checkbox"/>
	58	Jackson, W.F. et al., Prostacyclin-induced vasodilation in rabbit heart is mediated by ATP-sensitive potassium channels, <i>American Journal of Physiology</i> , 264(1 Pt 2):H238-43 (January 1993) (ABSTRACT ONLY)	<input type="checkbox"/>

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59	Kieler-Jensen, N. et al., Inhaled nitric oxide in the evaluation of heart transplant candidates with elevated pulmonary vascular resistance, Journal of Heart and Lung Transplant, 13(3): 366-375 (May-June 1994) (ABSTRACT ONLY)	<input type="checkbox"/>
60	Kurtz, A. et al., Mode of nitric oxide action on the renal vasculature, Acta Physiologica Scand, 168(1): 41-45 (January 2000) (ABSTRACT ONLY)	<input type="checkbox"/>
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62	Patel, A.I. et al., Activation of guanosine 3', 5'-cyclic monophosphate (cGMP)-dependent protein kinase in rat vas deferens and distal colon is not accompanied by inhibition of contraction, Journal of Pharmacology and Experimental Therapeutics, 283(2): 894-900 (November 1994) (ABSTRACT ONLY)	<input type="checkbox"/>
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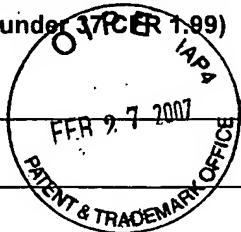
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**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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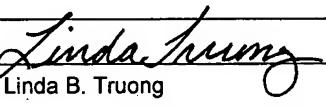
That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to  any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

OR

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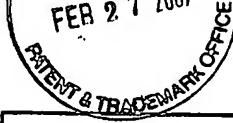
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Signature		Date (YYYY-MM-DD)	2007-02-21
Name/Print	Linda B. Truong	Registration Number	56461

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Form 1449 <sup>*</sup> INFORMATION DISCLOSURE STATEMENT		Docket Number: CEDAR 043453	Application Number: 09/491,500
IN AN APPLICATION (Use several sheets if necessary)		Applicant: Keith L. Black and Nagendra S. Ningaraj	
		Filing Date: Jan. 26, 2000	Group Art Unit: 1646



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EXAMINER	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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FORM 1449 <sup>®</sup> INFORMATION DISCLOSURE STATEMENT			Docket Number: CEDAR 043453	Application Number: 09/491,500
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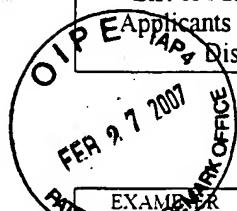
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List of Patents and Publications for Applicants Supplemental Information Disclosure Statement		
	APPLICANT: <b>Black et al.</b>	
	FILING DATE: <b>January 26, 2000</b>	GROUP ART UNIT <b>1633</b>



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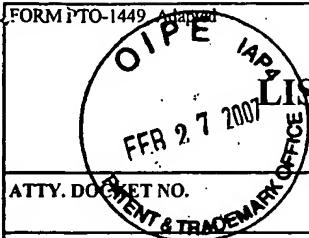
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES	TRANSLATION NO
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	WO 00/23102	27.04.00	PCT				
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